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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/727,874	12/01/2000	David C. Turner	VTN-518	4049

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EXAMINER

SIMONE, CATHERINE A

ART UNIT	PAPER NUMBER
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1772

5

DATE MAILED: 12/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/727,874

Applicant(s)

TURNER ET AL.

Examiner

Catherine Simone

Art Unit

1772

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 1-5 and 16-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 6-15 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Claims 1-5 and 16-19 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 4.

Applicant's election without traverse of claims 6-15 in Paper No. 4 is acknowledged.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. **Claims 6-15** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation "wherein periodic structures on the surface are of a periodicity of less than about 3 μm " in claim 6 is deemed vague and indefinite. What is meant by "periodic structures" and "periodicity"? Clarification is requested.

The recitations "amplitude" and "RMS" in claim 1 are deemed vague and indefinite. Clarification is requested.

The recitation "Group Transfer Product" in claims 12 and 13 is deemed vague and indefinite. Clarification is requested.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. **Claims 6-11** are rejected under 35 U.S.C. 103(a) as being unpatentable over Nicolson et al. (5,849,811).

Nicolson et al. discloses a silicone hydrogel contact lens comprising at least one surface (see col. 6, lines 1-6). However, Nicolson et al. fails to disclose an amplitude of less than about 4 nm. However, Nicolson et al. teaches an amplitude (see col. 17, lines 37-41). Therefore, the optimum amplitude would be readily determined through routine experimentation by one having ordinary skill in the art depending on the desired end results.

Furthermore, it would have been obvious to one of ordinary skill in the art at the time the applicant's invention was made to have provided an amplitude of less than about 4 nm in Nicolson et al., since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art absent of showing unexpected results. *In re Boesch and Slaney*, 205 USPQ 215 (CCPA 1980).

Regarding **claim 7**, note the at least one surface further comprises a hydrophilic coating (see col. 6, lines 1-3). Regarding **claims 8 and 11**, note the hydrophilic coating is poly(hydroxyethylmethacrylate) (see col. 20, lines 2-3). Regarding **claim 9**, note the hydrophilic coating is poly(acrylic acid) (see col. 27, line 48). Regarding **claim 10**, note the hydrophilic coating is poly(acrylamide) (see col. 7, lines 15-18).

6. **Claims 12 and 13** are rejected under 35 U.S.C. 103(a) as being obvious over Nicolson et al. (5,849,811) in view of Maiden et al. (6,367,929) and in further view of Bonafini, Jr. (5,923,397).

The applied reference (Maiden et al.) has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Nicolson et al. discloses a silicone hydrogel contact lens comprising at least one surface wherein the silicone hydrogel comprises 2-hydroxyethyl methacrylate (see col. 27, line 52), methyl methacrylate (see col. 27, line 17), methacryloxypropyl-tris(trimethylsiloxy)silane (see col. 6, lines 15-17), and N,N-dimethyl acrylamide (see col. 27, line 45). However, Nicolson et al.

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fails to disclose mono-methacryloxypropyl terminated mono-butyl terminated polydimethylsiloxane and a polymerizable mixture comprising a Si₇₋₉ monomethacryloxy terminated polydimethyl siloxane and tetraethyleneglycol dimethacrylate. Maiden et al. teaches in the analogous art mono-methacryloxypropyl terminated mono-butyl terminated polydimethylsiloxane (see col. 6, lines 56-57) and a polymerizable mixture comprising a Si₇₋₉ monomethacryloxy terminated polydimethyl siloxane (see col. 7, lines 10-11) and Bonafini, Jr. teaches in the analogous art tetraethyleneglycol dimethacrylate (see col. 5, line 52) for the purpose of producing a silicone hydrogel for use in contact lenses.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the applicant's invention was made to have provided mono-methacryloxypropyl terminated mono-butyl terminated polydimethylsiloxane and a polymerizable mixture comprising a Si₇₋₉ monomethacryloxy terminated polydimethyl siloxane and tetraethyleneglycol dimethacrylate in Nicolson et al. as suggested by both Maiden et al. and Bonfini, Jr. in order to produce a silicone hydrogel for use in contact lenses.

7. **Claims 14 and 15** are rejected under 35 U.S.C. 103(a) as being unpatentable over Nicolson et al. (5,849,811) in view of Kunzler et al. (5,539,016).

Nicolson et al. discloses a silicone hydrogel contact lens comprising at least one surface (see col. 6, lines 1-6). However, Nicolson et al. fails to disclose the silicone hydrogel comprising a fluorosiloxane hydrogel. Kunzler et al. teaches in the analogous art a silicone hydrogel comprising a fluorosiloxane hydrogel (see col. 2, lines 5-7) for the purpose of producing contact lenses with improved deposit resistance.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the applicant's invention was made to have provided the a fluorosiloxane hydrogel in Nicolson et al. as suggested by Kunzler et al. in order to produce a contact lens with improved deposit resistantace.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The patents are cited for further teachings of silicone hydrogel lenses similar to that instantly disclosed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine Simone whose telephone number is (703) 605-4297. The examiner can normally be reached on 9:30-6:00.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon can be reached on (703) 308-4251. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.



Catherine Simone
Examiner
Art Unit 1772

December 11, 2002



HAROLD PYON
SUPERVISORY PATENT EXAMINER
1772

12/16/02